JAN 3 0 2004

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ABAXIS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K040115

1. Applicant Information:

Date Prepared:	January 15, 2004
Name:	Abaxis, Inc.
Address:	3240 Whipple Road Union City, CA 94587
Contact Person:	Dennis M. Bleile, PhD
Phone Number:	(510) 675-6515
Fax Number:	(510) 441-6150

2. Device Information:

Classification	Class I
Trade Name:	Piccolo® Magnesium Test System
Classification Name:	Magnesium Test system 862.1495

3. Identification of legally marketed device to which the submitter claims equivalence:

The following table identifies the legally marketed device to which Abaxis claims equivalence:

Predicate Device			
Predicate Device	**Manufacturer**	**510(k) Number**	**Date of SE Determination**
Magnesium Slides on the Vitros 950 Chemistry System	Johnson and Johnson Clinical Diagnostics	K861386	8/26/86

4. Description of the Device:

The Piccolo Renal Function Panel Plus Reagent Disc (which contains the Piccolo Magnesium Test System) is designed to separate a heparinized whole blood sample into plasma and blood cells. The disc meters the required quantity of plasma and

Summary of Safety and Effectiveness (continued)

diluent, mixes the plasma with diluent, and delivers the mixture to the reaction cuvettes along the disc perimeter. The diluted plasma mixes with the reagent beads, initiating the chemical reactions that are then monitored by the analyzer. Alternately, the disc may also be used with serum.

5. Statement of Intended Use:

The Piccolo Magnesium Test System (presently contained on the Renal Function Panel Plus Reagent Disc) used with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of magnesium in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

6. Summary of the technological characteristics of the new device in comparison to those of the predicate device:

Table 1 outlines the technological characteristics of the Piccolo Magnesium Test System in comparison to the legally marketed predicate device.

Table 1: Specification Comparison: Piccolo Magnesium Test System

	Piccolo Point-of-Care Chemistry Analyzer	**Vitros 950 Chemistry System**
Intended Use	Quantitative analysis of Magnesium	Quantitative analysis of Magnesium
Methodology	Enzymatic rate reaction	Colorimetric
Sample Type	Heparinized whole blood, heparinized plasma, and serum	Heparinized plasma, serum, and urine
Sensitivity	0.1 mg/dL	0.2 mg/dL
Reagents	Dry test-specific reagent beads	Dry, multilayered, analytical element coated on a polyester support (slide). Active ingredients: 1,2-bis(o-aminophenoxy)ethane-N,N,N', N'-tetraacetic acid (calcium chelator) and 1,5-bis(2-hydroxy-3,5-dichlorophenyl)-3-cyano-formazan (dye)
Temperature of Reaction	37°C	37°C
Calibration	Bar code with factory calibrated lot specific data	Calibrated periodically using calibrators supplied by vendor
Assay Range	0.1 – 8.0 mg/dL	0.2 – 10.0 mg/dL
Testing Environment	Professional use	Professional use
Sample Size	Approximately 100 µL	10 µL

Summary of Safety and Effectiveness (continued)

7. Brief discussion of the clinical and nonclinical tests relied on for a determination of substantial equivalence.

Tables 2 summarize the results of clinical and non-clinical tests performed using the Piccolo Magnesium Test System.

Linearity:

Table 2:
Summary of Linearity

	Magnesium
Slope	0.992
Intercept	-0.05
Corr. Coefficient	0.999

Precision:

Precision studies were designed to evaluate within-run and total precision of the Magnesium Test System when run on the Piccolo Point-of-Care Chemistry Analyzer.

Table 3:
Within-Run and Total Precision for Magnesium,
Assayed on the Piccolo Point-of-Care Chemistry Analyzer

Analyte	Within-Run (n = 80)	Total (n = 80)
Magnesium (mg/dL)		
Level 1		
Mean	1.9	1.9
SD	0.03	0.06
CV	1.7	3.4
Level 2		
Mean	3.9	3.9
SD	0.04	0.10
CV	1.0	2.6

Summary of Safety and Effectiveness (continued)

Sample Type Comparison:

A study was conducted to examine and compare heparinized venous whole blood and serum on the Piccolo® Point-of-Care Chemistry Analyzer.

Serum, heparinized plasma and heparinized whole blood comparability were established for magnesium.

8. Conclusions

The clinical and non-clinical tests performed for Magnesium, when run on the Piccolo Point-of-Care Chemistry Analyzer demonstrate that the test system is as safe, effective and performs as well as the legally marketed device identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 3 0 2004

Dennis M. Bleile, Ph.D.
Director of Assay Development
Abaxis, Inc.
3240 Whipple Road
Union City, CA 94587

Re: k040115
Trade/Device Name: Piccolo® Magnesium Test System
Regulation Number: 21 CFR 862.1495
Regulation Name: Magnesium test system
Regulatory Class: Class I
Product Code: JGJ
Dated: January 15, 2004
Received: January 20, 2004

Dear Dr. Bleile:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

12.0 INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): K040115

Device Name: **Piccolo® Magnesium Test System**

Intended Use:

The Piccolo Magnesium Test System (presently contained on the Renal Function Panel Plus Reagent Disc) used with the Piccolo Point-of-Care Chemistry Analyzer is intended to be used for the *in vitro* quantitative determination of magnesium in heparinized whole blood, heparinized plasma, or serum in a clinical laboratory setting or point-of-care location.

Indications for Use:

Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia and hypermagnesemia.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over- The Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Carol Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K040115